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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/459,522	12/13/1999	CHET M. CRUMP	041861-01500	1246

23556 7590 10/04/2004

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EXAMINER	
EREZO, DARWIN P	
ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/459,522	CRUMP ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18* is/are allowed.

6)☒ Claim(s) *1-17 and 19-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-17 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,343,857 to Schneider et al.

3. As to claims 1-10, 15-17 and 19-21, Schneider teaches an apparatus comprising a catheter **23**; a manifold **10**; and a valve **20,19** disposed in the manifold, the valve being configured to selectively limit the withdrawal of air form the ventilation circuit, wherein the valve is capable of being opened by the catheter upon contact therewith when the catheter is advanced (by advancing the catheter **23** without attaching **35** to the manifold); wherein the valve comprises at least one protrusion (tip of valve **20,19**) on at least one surface of the valve and wherein the valve is a flap; wherein the valve moves between a first, distal position (see Fig. 4), and a second, proximal position (see Fig. 2); wherein the flap is configured such that at least one protrusion on a proximal surface of the flap engages the catheter; wherein the apparatus further comprises a catch **19** to engage the flap as is drawn into the second, proximal position, and to retain the flap in the second position (member **19** engages flap **20**, as seen in Fig. 2, and retains flap **20** in the closed, second position); wherein the flap **20** is pivotably connected to the

manifold; wherein the flap is generally disk-shaped because the valve is located within port **15**, which is circular; wherein the valve has an open position (as seen in Fig. 4) and a closed position (as seen in Fig. 2) wherein friction maintains the valve in the closed position; wherein the valve has an aperture (as seen in Figure 4, where the catheter **23** passes through) and the flap disposed to selectively cover the aperture; wherein the apparatus has a collar **33** disposed in the manifold having an aperture; wherein the collar including a port **33** for injecting liquid; wherein the apparatus further comprises a suction catheter **23** having distal end; a protective sleeve **22** surrounding the catheter; a manifold **10,11** connected to the protective sleeve and having means for accommodating inspiration and expiration of respiratory gases **13,14**; and a valve **16** connected to the manifold and pivotally moveable with respect thereto for engaging the distal end of the catheter to minimize the amount of air being drawn thereinto responsive to suction through the catheter wherein the valve comprises a flap **20** and wherein the valve further comprises at least one protrusion (see attached figure) on a surface of the valve; wherein the valve comprising a pivotable flap **20**; wherein the wherein teaches a valve comprising an aperture (as seen in Figure 4, where the catheter **23** passes through); wherein the apparatus further comprises a locking member **19** disposed in communication with the flap **20** for selectively preventing movement of the flap (as seen in Fig. 2, member **19** engages flap **20** and prevents further movement inwardly) and wherein the locking member comprises a projection extending inwardly; and wherein the locking member comprises a force-fit coupling between the flap and the catheter.

4. As to claims 11-14, Schneider teaches an endotracheal catheter system comprising a catheter **23** having a distal end; a ventilator manifold **10** disposed in communication with the catheter such that the catheter may be advanced through the manifold into the respiratory system of the patient and withdrawn from the respiratory system of the patient through the manifold; and a valve **16** for at least partially occluding the distal end of the catheter (see Fig. 4), the valve being configured to frictionally engage the distal end and thereby occlude the distal end; and wherein the valve is capable of being directly opened by the catheter (by advancing the catheter **23** without attaching **35** to the manifold); wherein the valve comprises a flap **20** and wherein the valve further comprises at least one protrusion (see attached Figure) on at least one surface of the valve; wherein the flap **20** is configured to engage the distal end of the catheter via the protrusion (see Fig. 4); wherein the system further comprises a first wiper seal **24** and a second wiper seal **27** disposed about the catheter when the catheter is advanced in the manifold; wherein the catheter is retractable so that the distal end of the catheter is disposed proximally form the first wiper seal and distally from the second wiper seal.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneider et al in view of US 6,168,758 to Forsberg et al.

7. As to claims 22-25, Schneider fails to specifically teach the type of material the valve is constructed of. Forsberg et al. discloses a liquid assay device comprising a valve composed of polyether block amides (col. 6, lines 38-49). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any well known material, including the polyether block amides of Forsberg et al. or the recited limitations of the claims, because it is a mere substitution of one valve material for another. Also, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of choice. *Sinclair & Carroll Co. V. Interchemical Corp.*, 327, 65 USPQ 297 (1945) also note In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Allowable Subject Matter

8. Claim 18 is allowed over the prior art of record.

Response to Arguments

9. Applicant's arguments filed 10/24/03 have been fully considered but they are not persuasive. The Schneider reference still teaches a catheter that is fully capable of opening the valve by advancing the catheter **23** through the adapter to a point beyond opening **29** and attaching the adapter to the manifold. At this configuration, the catheter will open the catheter and not the manifold. It should be noted that the applicant's

amended limitation is merely functional and that the structural limitation of Schneider is fully capable of performing said function.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER